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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,860	08/29/2001	Richard E. Rothman	001107.00185	5063

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

MAIL DATE	DELIVERY MODE
11/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/940,860	ROTHMAN ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4-23,33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23 and 34* is/are allowed.

6)☒ Claim(s) *2,4-22 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Applicants' response to the office action field on September 21, 2007 has been considered and acknowledged.

Status of the Application

2. Claims 2, 4-23, 33-34 are pending. All arguments and amendment have been fully considered and deemed unpersuasive for the reasons that follow. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The action is made FINAL.

Response to arguments:

3. With regard to the rejection of claims 2, 4, 8, 20-22, and 33 under 35 USC 103(a) as being unpatentable over Steinman in view of Stratagene Catalog 1995, Applicants' arguments and exhibits A and B have been fully considered and found unpersuasive. Applicants' arguments are based on previous prior art (DeFelippes et al.) and argue that DeFilippes et al. Applicants also argue that AluI is not an equivalent of a type II enzyme, but rather it is a species of the type II enzyme as shown in exhibit A and assert that a claimed species or subgenus encompassed by the prior art is not sufficient by itself to establish a prima facie case of obviousness and DeFelippes teaches away from the instant invention. Applicants also argue that the rejection over Steinman in view of Stratagene should be withdrawn because the teachings of DeFelippes remain relevant to the assessment of non-obviousness. Applicants' arguments are fully considered and found unpersuasive because as stated in the previous office action Examiner reiterates that the situation in the instant rejection is not the same as in DeFelippes, First, the obviousness was made based on the ability of the type II restriction endonucleases to eliminate DNA contamination as shown

by Steinman et al. and the Stratagene Catalog was used to show that the AluI is an equivalent enzyme to said type II restriction endonucleases and it is obvious to one skilled in the art would have used such equivalent enzymes to eliminate DNA contamination in PCR reagents. Second, the arguments based on negative teachings of DeFelippes are irrelevant to the instant situation where the rejection is based on type II enzymes used to decontaminate the PCR reaction and Stratagene Catalog discloses equivalent type II enzymes. Thus the arguments based on the DeFelippes are not applicable to the instant context.

Applicants also argue that the instant invention is not drawn to a composition rather the claim the method employing Alu I, and Defelippes teaches away form the use of AluI and one skilled in the art would have recognized that all members of type II genus would not be suitable for decontaminating PCR reactions. Applicants' arguments on generalized statements on all members of type II genus not suitable for decontaminating PCR reaction is unpersuasive because the primary reference demonstrates the suitability of type II enzymes for decontaminating PCR reactions and the unappreciated property of use of Alu I and the claiming the new use of the composition is inherent and does not render the claims patentable. Thus the use of type II restriction endonucleases for complete elimination of DNA contamination in PCR reaction mixture is an inherent property of type II restriction endonucleases and use of such equivalent enzymes is considered obvious over the prior art.

Applicants also argue that if the use of type II enzymes in decontaminating PCR reactions is inherent property, one skilled in the art would have employed other equivalent type II enzymes as shown in the exhibit B rather than using AluI. Applicants' arguments are unpersuasive because Steinman did demonstrate the use of type II enzymes for the purpose of

decontaminating PCR reactions and Stratagene Catalog is used to show that the equivalent type II enzymes including AluI could be used as an enzyme having the inherent property. Examiner notes that Stratagene Catalog also shows other equivalent type II enzymes in addition to AluI. Therefore the rationale is to show that the other type II enzymes including AluI are equivalent to the type II enzymes taught by Steinman et al.

Further Applicants argue that the present claims do not recite optimum or workable ranges and the assertions of the office action mailed on March 19, 2007 are not applicable to the present claims. Applicants arguments are unpersuasive because the instant claims do not require to recite said terms, rather the instant method uses AluI and the rejection is based on obviousness-type rejection, wherein the instant claims are not distinguishable form the prior art cited thus if the use of AluI is other than a routine experimentation, as noted in *In re Aller*, 105 USPQ 233 at 235, no evidence has been presented by the Applicants to show that the use of AluI, a type II enzyme digestion performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art. As stated in MPEP 716.02 (d) "Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In re Clemens , 622 F.2d 1029, 206 USPQ 289, 296 (CCPA 1980)". Here, Steinman expressly teach use of type II restriction endonucleases to decontaminate PCR reaction mixture and Stratagene Catalog provides several equivalent type II restriction endonucleases that are within

the scope of the instant claims and there is no evidence or showing that the use of AluI is other than a routine optimization. Therefore for the reasons above, the rejection is maintained.

5. With regard to the rejection of claims 5-7 and 9-19 under 35 USC 103(a) as being obvious over Steinman in view of Stratagene, further in view of Hoshina, Applicants' arguments are found unpersuasive. Applicants argue that Hoshina does not cure the deficiencies of the two primary references and as shown previously in exhibits A-J, one skilled in the art would not have no reasonable expectation of success of the method as DeFelippes has shown unsuitability of AluI for PCR reagent decontamination. Applicants' arguments are found unpersuasive. If the AluI is not suitable for PCR reagent decontamination, the instant method using AluI would have resulted in similar results and if the use of said AluI is other than routine optimization, Applicants did not establish any unexpected results to show the use of AluI is other than routine optimization. Therefore as discussed in the previous office action and as discussed above it is obvious to combine the primary references with Hoshina, which does make the instant claims obvious. The rejection is maintained herein.

Conclusion

Claims 23 and 34 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner
Art Unit 1637.

Prabha Chunduru 11/21/07
SURYAPRABHA CHUNDURU
PRIMARY EXAMINER